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| 10/537,676 | 06/06/2005 | Shuji Hinuma | 10577.0003-00000 | 8346 |
| 22852 | 7590 | 01/24/2008 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | EXAMINER STOICA, ELLY GERALD | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,676

Applicant(s)

HINUMA ET AL.

Examiner

ELLY-GERALD STOICA

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8.9 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8.9 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

1. In the amendment filed on 11/26/2007, Applicant cancelled claims 1-7 and 10-21, amended claims 8 and 9, and added the new claims 22-24. Consequently, the claims 8-9 and 22-24 are pending and under examination.

Withdrawn claim rejections

Claim Rejections - 35 USC § 112

2. The enablement rejection of claims 8 and 9 under 35 USC § 112 1st paragraph, as well as the indefiniteness rejection of the claims 8 and 9 under 35 USC § 112 2nd paragraph are withdrawn in view of the amended claims.

Maintained and new claim rejections necessitated by amendment

Claim Rejections - 35 USC § 112

3.

Claim Rejections - 35 USC § 102

4.3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 9 remain rejected and claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (U.S. Pat. 6, 485,922, 11/26/2002). As iterated in the previous Office action, Erickson et al. teach a method for identifying compounds which modulate the activity of any of the EDG receptors, comprising the steps of exposing a compound and LPA to the EDG-2 receptor coupled to a response pathway, under conditions and for a time sufficient to allow interaction of LPA with the EDG-2 receptor and an associated response through the pathway, and b) detecting an increase or a decrease in the stimulation of the response pathway, relative to the absence of the tested compound (col. 6 from line 28 to col. 7, line 42). The Seq. Id. of the receptor mentioned by Erickson et al, Seq. Id No: 20, is identical to Seq. Id. No.: 1 of the instant application. Since the detection of any activation of the EDG-2 receptor is necessarily linked to the binding of the LPA to the EDG-2 receptor, the limitations of the claim 8 and 9 is present in Erickson et al. Moreover, the intended use of the binding altering drug thus uncovered is not a precondition of the method so that the claims of the instant Application are anticipated by Erickson et al.

On page 12 of the Remarks Applicants argue that Erickson et al. does not teach or suggest a test that identifies a compound that inhibits mesangial cell growth.

The arguments were carefully considered but not found persuasive because the test performed by Erickson et al. would identify compounds that modulate the activity of

EDG receptors. Unless the Applicant presents experimental evidence that the EDG-2 receptor found on mesangial cells is different than the EDG-2 receptor known in the art and claimed by Erickson et al., difference that is nowhere presented in the Specification, the claimed method is no different than the method of Erickson et al. Inhibiting proliferation of mesangial cells by antagonistic action of a compound binding to EDG-2 receptor is linked to signal transduction events which occur in all cells expressing the receptor and is not unique to mesangial cells. Therefore the method of screening of Erickson et al. would necessarily anticipate the method of screening of the instant Application.

Claims 8 and 9 remain rejected and claims 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (U.S. Pat. 6,875,757 04/05/2005).

As presented in the Office Action of 07/29/2007, Miller et al. teach method of modulating LPA activity on an LPA receptor which includes providing a compound of the present invention which has activity as an LPA receptor antagonist and contacting an LPA receptor with the compound under conditions effective to inhibit LPA-induced activity of the LPA receptor (col. 8, lines 10-40). One of the LPA receptors is EDG-2 (fig. 1). Again, any LPA activity through EDG-2 is in the wake of LPA binding to the EDG-2 receptor and thus the limitation existent in the claims of the instant Application is met.

On page 14 of the Remarks Applicants argue that Miller et al. does not teach or suggest a test that inhibits mesangial cell growth. Inhibiting proliferation of mesangial cells by antagonistic action of a compound binding to EDG-2 receptor is linked to signal

transduction events which occur in all cells expressing the receptor and is not unique to mesangial cells. Therefore the method of screening of Miller et al. would necessarily anticipate the method of screening of the instant

The arguments were carefully considered but not found persuasive because the test performed by Miller et al. would identify compounds that modulate the activity of LPA receptors. Unless the Applicant presents experimental evidence that the LPA receptor found on mesangial cells is different than the LPA receptor (EDG-2 receptor) taught by claimed by Miller et al., difference that is nowhere presented in the specification, the claimed method is no different than the method of Miller et al. while the intended use of the compound is not given patentable weight.

Conclusion

5.4. No claims are allowed.

6.5. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/